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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/837,678	04/18/2001	David Ogle		7858

7590

07/15/2004

James D. Jacobs, Esq.  
Baker & McKenzie  
805 Third Avenue  
New York, NY 10022

EXAMINER
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NOGUEROLA, ALEXANDER STEPHAN

ART UNIT	PAPER NUMBER
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1753

DATE MAILED: 07/15/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 09/837,678	<b>Applicant(s)</b> OGLE ET AL.	
	<b>Examiner</b> ALEX NOGUEROLA	<b>Art Unit</b> 1753	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 12 May 2004.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1,3-15 and 17-36 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,3-15,17-32,35 and 36 is/are rejected.
- 7) ☒ Claim(s) 29, 31, 33, and 34 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 18 April 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \*    c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Response to Amendment***

1. Applicants' amendment of May 12, 2004 does not render the application allowable.

### ***Response to Arguments***

2. Applicants traverse the rejections of claims 1-11, 14-25, 28-32, 35, and 36 under 35 U.S.C. § 103(a) as being unpatentable over Speicher et al. (US 6,638,408) in view of Murakawa et al. (JP 03-118462 A) (page 11 of the amendment of May 12, 2004). The examiner respectfully is not persuaded by Applicants' traversal. First, claims 1-11, 14-25, 28-32, 35, and 36 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Murakawa et al. (JP 03-118462 A) in view of Speicher et al. (US 6,638,408) (page 13 of the Office action of November 13, 2003, "Office action"), not over Speicher et al. in view of Murakawa et al. Second, unlike Speicher et al., Murakawa et al. does not use isoelectric membranes. Murakawa et al. uses molecular-weight partitioning membranes (abstract). Last, Speicher et al. can be reasonably combined with Murakawa et al. because Speicher et al. is primarily relied upon to show that it was known at the time of invention to scale down to 5 ml or less compartments in an electrophoresis device that are formed by spaced membranes. The type of membrane Speicher et

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al. uses is immaterial to his teaching of a small-scale electrophoresis device having compartments formed by membranes. Scaling a device to make it larger or smaller is in itself prima facie obvious (*In re Rose*, 105 USPQ 237 and *In re Reven*, 156 USPQ 679). Speicher et al. just supports the obvious scaling by showing that at the time of the invention electrophoresis devices having membrane compartments were known with dimensions on the order of those claimed by Applicants. As stated in the Office action, "it would have been obvious to scale the apparatus to accommodate a sample volume within the expected volume range" (page 14 of the Office action).

***Status of Objections and Rejections Pending Since the Office action of November 13, 2003***

3. The objections to claims 5 and 19 are withdrawn.
4. The objections to claims 29 and 31 are maintained.
5. All of the rejections under 35 U.S.C. §112, second paragraph, are withdrawn.
6. The rejections of claims 1-3, 5-10, 12-17, 19-24, 26-30, 32, 35, and 36 as being anticipated under 35 U.S.C. § 102(e) by Speicher et al. are withdrawn.

7. The rejections of claims 1-11, 14-25, 28-32, 35, and 36 as being obvious under 35 U.S.C. § 103(a) over Murakawa et al. in view of Speicher et al. have been withdrawn, but are largely rewritten below in light of Applicants' amendments.

8. The rejections of claims 4, 18, and 31 as being obvious under 35 U.S.C. § 103(a) over Speicher et al. have been withdrawn.

***Claim Rejections - 35 USC § 103***

9. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

10. Claims 1, 3-15, 17-32, 35, and 36 are rejected under 35 U.S.C. 103(a) as being unpatentable over the Derwent abstract and Figure 1 of Murakawa et al. (JP 03118462 A) in view of Speicher et al. (US 6,638,408 B1).

Addressing claims 1, 3, and 4, the Murakawa et al. reference teaches an apparatus for processing compounds (abstract and Fig. 1) comprising:

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- (a) a cathode (**2** in Fig. 1) in a static cathode buffer zone;
- (b) an anode (**3**) in a static anode buffer zone, the anode disposed relative to the cathode so as to be adapted to generate an electric field in an electric field area therebetween upon application of a voltage potential between the cathode and anode;
- (c) a first non-isoelectric separation barrier (**5**) disposed in the electric field area;
- (d) a second non-isoelectric separation barrier (**6**) disposed between a selected one of the cathode buffer zone and the anode buffer zone and the first barrier so as to define a first interstitial volume (**4b**) therebetween;

wherein in use, electrophoretic buffer is disposed in the cathode buffer zone and the anode buffer zone, a sample containing one or more compounds is provided to the first chamber, wherein upon application of the voltage potential, a selected compound is removed from the sample through one of the first or second non-iso-electric separation barriers, and provided to one of the cathode buffer zone or the anode buffer zones; and wherein there is substantially no circulation of buffer or sample in the buffer zones or the first interstitial chamber (abstract and Fig. 1).

The Murakawa et al. reference does not mention whether the apparatus is configured for small sample volumes. The Speicher et al. reference teaches an apparatus for separating molecules using an electric field, the apparatus having an anode, a cathode, and several separation membranes and when used the apparatus does not circulate the anode buffer, the cathode buffer, or sample constituents. The apparatus of the Speicher et al. reference is clearly configured for small sample volumes as the reference teaches compartments formed by separation membranes each having a volume of less than 5 ml. It would have been obvious to

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one with ordinary skill in the art at the time the invention was made to scale the apparatus to process a small sample volume as taught by the Speicher et al. reference in the invention of the Murakawa et al. reference, by having, for example the interstitial volume be 5ml or less, 2ml or less, or from about 0.02 ml to 0.1 ml, because this will optimize the apparatus for separations on small sample volumes. In other words, it would have been obvious to scale the apparatus to accommodate a sample volume within the expected sample volume range.

Addressing claims 5-8 and 18-22, barring a contrary showing, the claimed ratios of interstitial volume to barrier surface area are just optimized ranges for intended sample volume ranges. Applicant should note that Speicher et al. discloses a large range for the membrane area (col. 6, ll. 49-53), which would have suggested to one with ordinary skill in the art at the time of the invention to scale the device to best accommodate the expected sample volume range.

Addressing claims 9, 10, 23, and 24, although Murakawa et al. does not mention the pore size of the membranes (note that only the abstract is currently available to the examiner), as seen in col. 4, ln. 55 – col. 5, ln. 54, especially col. 5, ll. 44-46, Speicher et al. discloses various separation barriers, which are electrophoresis membranes, including a membrane made of polyacrylamide that is permeable to small ions and has a molecular weight cut-off of 1kDa. It would have been obvious to one with ordinary skill in the art at the time the invention was made to use electrophoresis membranes with a molecular weight cut-off of 1 kDa as taught by the Speicher et al. reference in the invention of the Murakawa et al. reference if molecules with a

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molecular weight of about 1 kDa are to be separated out because the molecular weight cut-off of the membrane should be the same as molecular desired molecular-weight separation threshold for the molecules.

Addressing claims 11 and 25, the Murakawa et al. reference teaches using membranes with different molecular weight cut-offs to separate larger molecules of interest from smaller molecules (abstract). At the time of the invention polyacrylamide was a commonly used electrophoresis separation material.

Addressing claims 12 and 26, although Murakawa et al. does not mention particular membrane materials (note that only the abstract is currently available to the examiner), as seen in col. 5, ln. 55 – col. 6, ln. 3 and col. 6, ll. 62-67, Speicher et al. discloses various separation barriers capable of being used as an ultrafiltration material, an electrodialysis material, or a haemodialysis material. Since Murakawa et al. uses the membranes to filter molecules it would have been obvious to one with ordinary skill in the art to consider membranes and filter materials used in related arts, such as electrodialysis, which is closed related to electrophoresis in that it uses an electric field to separate charged species. The choice of membrane material will depend primarily on its pore size and its suitability for the chemical environment in which the separation is to occur.



Addressing claims 13 and 27, although Murakawa et al. does not mention whether “the first and second separation barriers are adapted to be removed from the apparatus.” It would have been obvious to one with ordinary skill in the art so adapt the separation barriers 1. because then the membranes may be removed so that molecules trapped in them can be eluted, which is taught by Speicher et al. (col.16, ll. 48-50).

Addressing claim 14, the Murakawa et al. reference also does not mention “a plurality of separation barriers spaced apart defining a plurality of interstitial volumes” The Speicher et al. reference teaches providing a plurality of separation membranes (Figure 1). It would have been obvious to one with ordinary skill in the art at the time the invention was made to provide a plurality of separation membranes as taught by the Speicher et al. reference in the invention of the Murakawa et al. reference because then several separation compartments can be formed. Thus, the sample constituents can be then divided into several subgroups each limited in range along one separation property, rather than just one subgroup, so more selective partitioning of the sample constituents can be obtained. Indeed, the Murakawa et al. reference provides for at least two molecular-weight partitioning films (abstract). As for having an interstitial volume of less than 5 ml, again, it would have been obvious to one with ordinary skill in the art at the time of the invention to scale the apparatus to accommodate a sample volume within the expected volume range.

Addressing claims 15, 17, and 18 the Murakawa et al. reference teaches an electrophoresis apparatus for processing compounds (abstract and Fig. 1) comprising:

- (a) a cathode (**2** in Fig. 1) in a static cathode buffer zone;
- (b) an anode (**3**) in a static anode buffer zone, the anode disposed relative to the cathode so as to be adapted to generate an electric field in an electric field area therebetween upon application of a voltage potential between the cathode and anode;
- (c) a first non-isoelectric separation barrier (**5**) disposed in the electric field area;
- (d) a second non-isoelectric separation barrier (**6**) disposed between a selected one of the cathode buffer zone and the anode buffer zone and the first barrier so as to define a first chamber having an interstitial volume (**4b**) therebetween;

wherein in use, electrophoretic buffer is disposed in the cathode buffer zone and the anode buffer zone, a sample constituent is provided to the first chamber, wherein upon application of the voltage potential, a selected compound is removed from the sample through a selected one of the first and second separation barriers, and provided to a selected one of the cathode buffer and anode buffer zones; and wherein there is substantially no circulation of buffer or sample in the buffer zones or the first chamber (abstract and Fig. 1).

Murakawa et al. does not mention whether the apparatus is configured for small sample volumes. Speicher et al. teaches an apparatus for separating molecules using an electric field, the apparatus having an anode, a cathode, and several separation membranes and when used the apparatus does not circulate the anode buffer, the cathode buffer, or sample constituents. The apparatus of Speicher et al. is clearly configured for small sample volumes as the reference

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teaches compartments formed by separation membranes each having a volume of less than 5 ml. It would have been obvious to one with ordinary skill in the art at the time the invention was made to scale the apparatus to process a small sample volume as taught by Speicher et al. in the invention of Murakawa et al., such as by having an interstitial volume of less than 5 ml, 2ml or less, or from about 0.02 ml to 0.1 ml, because this will optimize the apparatus for separations on small sample volumes. In other words, it would have been obvious to scale the apparatus to accommodate a sample volume within the expected volume range.

Murakawa et al. also does not mention "a third separation barrier disposed between the anode buffer zone and the first barrier so as to define a second chamber having an interstitial volume." Speicher et al. teaches providing a third separation membrane (Figure 1). It would have been obvious to one with ordinary skill in the art at the time the invention was made to provide a third membrane as taught by Speicher et al. in the invention of Murakawa et al. because then several separation compartments can be formed. Thus, the sample constituents can be then divided into several subgroups each limited in range along one separation property, rather than just one subgroup, so more selective partitioning of the sample constituents can be obtained. Indeed, the Murakawa et al. reference provides for at least two molecular-weight partitioning films (abstract).

Addressing claim 28, Murakawa et al. teaches an electrophoresis apparatus for processing compounds (abstract and Fig. 1) comprising:

- (a) a cathode (2 in Fig. 1) in a static cathode buffer zone;
- (b) an anode (3) in a static anode buffer zone, the anode disposed relative to the cathode so as to be adapted to generate an electric field in an electric field area therebetween upon application of a voltage potential between the cathode and anode;
- (c) a first non-isoelectric separation barrier (5) disposed in the electric field area;
- (d) a second non-isoelectric separation barrier (6) disposed between the cathode buffer zone and the first barrier so as to define a first sample chamber having an interstitial volume (4b) therebetween;

wherein in use, electrophoretic buffer is disposed in the cathode buffer zone and the anode buffer zone, and the first sample chamber, a sample containing one or more compounds is provided to the first sample chamber, wherein upon application of the voltage potential, a selected compound is removed from the sample through the first separation barrier, and; and wherein there is substantially no circulation of buffer or sample constituent in the buffer zones or the first sample interstitial volume (abstract and Fig. 1).

Murakawa et al. does not mention whether the apparatus is configured for small sample volumes. Speicher et al. teaches an apparatus for separating molecules using an electric field, the apparatus having an anode, a cathode, and several separation membranes and when used the apparatus does not circulate the anode buffer, the cathode buffer, or sample constituents. The apparatus of the Speicher et al. reference is clearly configured for small sample volumes as the reference teaches compartments formed by separation membranes each having a volume of less

than 5 ml. It would have been obvious to one with ordinary skill in the art at the time the invention was made to scale the apparatus to process a small sample volume as taught by the Speicher et al. reference in the invention of the Murakawa et al. reference, by having the first interstitial volume 5ml or less, for example, because this will optimize the apparatus for separations on small sample volumes. In other words, it would have been obvious to scale the apparatus to accommodate a sample volume within the expected volume range.

Murakawa et al. also does not mention "a third non-isoelectric separation barrier disposed between the anode buffer zone and the first barrier so as to define a first separation chamber having interstitial volume." Speicher et al. teaches providing a third separation membrane (Figure 1). It would have been obvious to one with ordinary skill in the art at the time the invention was made to provide a third membrane as taught by Speicher et al. in the invention of Murakawa et al. because then several separation compartments can be formed. Thus, the sample constituents can be then divided into several subgroups each limited in range along one separation property, rather than just one subgroup, so more selective partitioning of the sample constituents can be obtained. Indeed, the Murakawa et al. reference provides for at least two molecular-weight partitioning films.

Addressing claims 29, 30, and 32 as stated in the rejection of claim 28, the Murakawa et al. reference provides for at least two molecular-weight partitioning films. Barring evidence to the contrary, such as unexpected results, the number of separation barriers will depend on the number of compartments desired; that is, on the number of subgroups into which the sample constituents is to be divided. As for having an interstitial volume of less than 5 ml, again, it

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would have been obvious to one with ordinary skill in the art at the time of the invention to scale the apparatus to accommodate a sample volume within the expected volume range.

Addressing claim 31, a second cathode and a second anode as claimed is just mere duplication of parts. It would have been obvious to one with ordinary skill in the art at the time of the invention to provide a second cathode and a second anode as claimed because then two samples may be simultaneously separated by electrophoresis in independent electrophoresis units. Note that Applicant's claim language does not require electrophoresis units with shared membranes as in Figure 6, but reads on two independent electrophoresis units as in Figure 3.

Addressing claims 35 and 36, separating a compound in small volumes of solution is taught in the abstract. The claim steps of adding anode and cathode buffer, introducing a sample into the apparatus, and applying a voltage potential are clearly necessary in order to use the apparatus for separating a compound in a sample volume.

#### ***Allowable Subject Matter***


11. Claims 33 and 34 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. The allowability of these claims has been addressed in the Office action of November 13, 2003.

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12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to ALEX NOGUEROLA whose telephone number is (571) 272-1343. The examiner can normally be reached on M-F 8:30 - 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, NAM NGUYEN can be reached on (571) 272-1342. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
Alex Noguerola  
Primary Examiner  
AU 1753  
July 13, 2004